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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,985	11/03/2000	Dirk M. Anderson	2874-B	6890

7590 11/04/2002

Immunex Corporation
Law Department
51 University Street
Seattle, WA 98101

EXAMINER
BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/705,985	Anderson et al
Examiner	**Art Unit**
Nirmal S. Basi	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 13, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5, 9, 11, 13, 15-18, 20, 21, 25, and 26* is/are pending in the application.

4a) Of the above, claim(s) *1-4, 17, and 21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *5, 9, 11, 13, 15, 16, 18, 20, 25, and 26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3 and 1(*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Preliminary Amendment filed 11/3/00 (paper number 2), 7/30/01 (paper number 4), Response to Restriction requirement filed 6/24/02 (paper number 8), statement under 37 CFR 1.821 and 1.825 filed 6/24/02 (paper number 9) and IDS filed 9/13/02 (paper number 10) have been entered.

Election/Restriction

2. Applicant's election without traverse of Group III, claims 5-16, 18-20 and 22-24 in Paper No. 8 (6/24/02), to the extent that they encompass a method of ameliorating the affects of excess bone loss comprising administering RANK polypeptide of SEQ ID NO:2, is acknowledged. Claims 1-4, 17, 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected. Applicant has canceled claims 6,-8, 10, 12, 19, 22-24 and added new claims 25 and 26. Newly added claims 25 and 26 will be examined.

Claim Rejection, 35 U.S.C. 112

3. Claims 5, 9, 11, 13, 15, 16, 18, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 13 are indefinite because it is not clear what is ameliorating effects of excess bone loss so as to allow the metes and bounds of the claim to be determined. Ameliorate means to make better or more tolerable. It is not clear what effects of excess bone loss are made better or made more tolerable. Also it is not clear what RANK activity is inhibited.

Claim 11 is indefinite because it does not further limit claim 9 from which it depends. Claim 9 depends on claim 5, which has the limitation of "a polypeptide comprising amino acids 33-213 of SEQ ID NO:2". Claim 11 has the limitation " polypeptide comprises an amino acid sequence that is at least 80% identical in amino acid sequence to amino acids 33-213 off SEQ ID NO:2, said is broader in scope than the base claim. Similarly claim 15 is broader in scope than the base claim 13 by reciting the limitation of " polypeptide comprises an amino acid sequence that is at least 80% identical in amino acid sequence to amino acids 33-213 off SEQ ID NO:2".

Claim 5 is indefinite because it is not clear what determines if a patient is at risk from having the conditions disclosed in the claim so as to allow the metes and bounds of the claims to be determined.

Claims 9, 16, 18, 20 and 25-26 are rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

4. Claims 5, 9, 11, 13, 15, 16, 18, 20, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing osteoclast differentiation by administering a soluble RANK polypeptide disclosed in the claims to a patient that suffers squamous cell carcinoma, does not reasonably provide enablement for ameliorating effects of excess bone loss in patients that at risk or suffer from a condition selected from the group consisting of bone cancer, multiple myeloma, melanoma and brest cancer, lung cancer, prostate cancer, hemolytic cancer, head and neck cancer and renal cancer. The, specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses RANKl LZ induces osteoclast differentiation in the presence of CSF-1, the combination of CSF-1 and RANKL is required for the generation of osteoclast, osteoclast differentiating activity is of RANKL is mediated through RANK, MH-85 and OKK squamous cells express RANKL and MH-85 cells also express CSF-1, CSF-1 upregulates RANK interaction with RANKL, signals transduced by RANK and RANKL interaction result in increased numbers of mature osteoclasts and bone breakdown. Therefore based on the specification soluble forms of RANK would inhibit RANK/RANKL interaction thereby reducing osteoclast differentiation in individuals with increased osteoclast differentiation resulting from squamous cell carcinoma. The claims encompass ameliorating the effects of excess bone loss in a wide variety of diseases. There is no support in the specification or prior art that RANK administration will ameliorate effects of excess bone loss, or even if all the individuals encompassed by the claimed disease states have increased osteoclast differentiation as result of upregulation of RANK by CSF-1, or even if the cancers in said individuals also express increases in CSF-1 which will result in increased osteoclast differentiation. Further, claims 13, 15, 16, 18,25 and 26 are rejected based on the failure of the specification to enable one of skill in the art to make and/or use the method for therapeutically ameliorating the effects of excess bone loss in a subject in need thereof, said method comprising the step of administering to said subject a therapeutically sufficient amount of a composition comprising a RANK polypeptide. The composition comprising inhibitor of RANK polypeptide infers a drug

or medication with therapeutic activity. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim without undue experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (8 USPQ2d 1400 (CA FC 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The term "therapeutically composition" implies a treatment of a disease. It is unpredictable what diseases could be effectively treated using a RANK polypeptide. The relationship to the treatment of a specific disease state are not disclosed, only that Rank reduces osteoclast differentiation in squamous cell in culture. Neither the specification nor the prior art provide sufficient guidance as to what specific diseases could be treated by administering RANK. Attempting to identify a disease treatable by RANK would constitute undue experimentation. Therefore one of skill in art would have to identify a disease treatable by said RANK, determine effective compositions, determine effective doses to achieve the intended purpose, determine routes of effective administration, determine if the RANK can reach its target tissue without degradation and determine if it has a therapeutic effect, all of which would constitute undue experimentation Therefore, the unpredictability to achieve all the afore mentioned goals and the lack of guidance provided in the specification, the disclosure fails to enable one of skill in the art how to make and/or use the method of therapeutically ameliorating the effects of excess bone loss in the wide variety of cancers disclosed in the claims.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
October 21, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600